

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450



IAP10 Rec'd PCT/PTO 30 NOV 2005

Docket No.: 478.1072
Date: November 28, 2005

In re application of: John N. STANIFORTH, et al.
Serial No.: 10/552,231
Filed: October 6, 2005
For: **PHARMACEUTICAL COMPOSITIONS COMPRISING APOMORPHINE FOR PULMONARY INHALATION**

Sir:

Transmitted herewith is an **Information Disclosure Statement** in the above-identified application.

- ☐ Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a verified statement previously submitted.
- ☐ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.
- ☐ No fee for additional claims is required.
- ☒ Also transmitted herewith are:
- ☐ Petition for extension under 37 C.F.R. 1.136 (in duplicate)
- ☒ Other: Form PTO-1449 (7 pages);
Complete set of references cited;
Appendix A, includes International Search Report issued in International Application No. PCT/GB2004/001627; and
Return Postcard.
- ☐ Check(s) in the amount of \$. 00 is/are attached to cover:
- ☐ Filing fee for additional claims under 37 C.F.R. 1.16
- ☐ Petition fee for extension under 37 C.F.R. 1.136
- ☐ Other:
- ☒ The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.
- ☒ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
- ☒ Any patent application processing fees under 37 C.F.R. 1.17.
- ☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith; and it is hereby requested that this be a petition for an automatic extension of time under 37 C.F.R. 1.136.

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UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: To be assigned

Art Unit: To be assigned

Re: Application of:

John N. STANIFORTH, et al.

Serial No.:

10/552,231

Filed:

October 6, 2005

For:

**PHARMACEUTICAL
COMPOSITIONS COMPRISING
APOMORPHINE FOR
PULMONARY INHALATION****INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.56**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

November 28, 2005

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (7 sheets) for consideration by the Examiner in connection with the above-identified patent application.

In accordance with 37 C.F.R. § 1.98(a)(2), copies of non-patent publications and foreign patents are enclosed. If it is determined that any of these references are not enclosed, the Examiner is requested to contact the undersigned so that a missing copy can be provided.

Pursuant to the waiver of the requirement under 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. patents and applications are not enclosed.

The Examiner's attention is directed to references "GH", "GI" and "GL" on sheet 7 of the enclosed Form PTO-1449. These references were cited in the International

Search Report issued in International Application No. PCT/GB2004/001627, a copy of the Search Report is enclosed as Appendix A.

Applicants also respectfully advise the Examiner of the following co-pending U.S. patent applications which are commonly assigned to the owners of the instant application:

U.S. Patent Application Serial No. 10/413,022, entitled "Composition, Device, and Method for Treating Sexual Dysfunction Via Inhalation," filed April 14, 2003; and

U.S. Patent Application Serial No. 10/621,964, entitled "Composition, Device and Method for Treating Sexual Dysfunction Via Inhalation," filed July 17, 2003.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 (7 sheets) be considered and made of record.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97 (b), before the mailing of a first Office Action on the merits. Accordingly, it is believed that no fee is due. In the event any additional fee is due or any overpayment made in connection with the filing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge said deficiency or credit overpayment to our Deposit Account No. 50-0552.

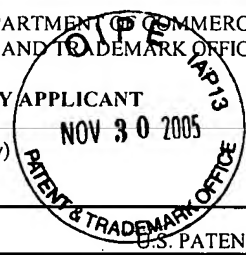
Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

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| --FORM PTO-1449 (REV. 7-80) | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO.: 478.1072 | | SERIAL NO.: 10/552,231 | |
| LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary) | | | | APPLICANT(S): John STANIFORTH et al. | | | |
| | | | | FILING DATE: October 6, 2005 | | GROUP: To be assigned | |



| U.S. PATENT DOCUMENTS | | | | | | | | | | | | |
|-----------------------|-----------------|----------|--------------------|-------|----------|----------------------------|--|--|--|--|--|--|
| *EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE | | | | | | |
| AA | 4 5 2 1 4 2 1 | 06/04/85 | Foreman | 514 | 267 | 09/26/83 | | | | | | |
| AB | 4 6 8 7 7 7 3 | 08/18/87 | Neumeyer, et al. | 514 | 280 | 05/31/85 | | | | | | |
| AC | 5 2 9 2 5 2 0 | 03/08/94 | de Haan, et al. | 424 | 465 | 08/31/92 | | | | | | |
| AD | 5 4 4 1 7 4 7 | 08/15/95 | de Haan, et al. | 424 | 465 | 02/09/94 | | | | | | |
| AE | 5 7 5 6 4 8 3 | 05/26/98 | Merkus | 514 | 58 | | | | | | | |
| AF | 5 7 7 0 6 0 6 | 06/23/98 | El-Rashidy, et al. | 514 | 284 | 10/20/95 | | | | | | |
| AG | 5 9 4 5 1 1 7 | 08/31/99 | El-Rashidy, et al. | 424 | 430 | 01/30/98 | | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | | | |
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| DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | | | | |
| | | | | | YES | NO | | | |
| AH | 9 4 2 2 4 4 5 | 10/13/94 | WO (A2) | A61K | 31/48 | | | | |
| AI | | | | | | | | | |
| AJ | | | | | | | | | |
| AK | | | | | | | | | |

| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | |
|--|---|
| AL | Padma-Nathan, "Oral Drug Therapy for Female Sexual Dysfunction", Intl J of Impotence Research, Vol 12 Supp 3 (2000) pp S56 -S57 |
| AM | Alexander-Williams, et al., "Novel routes of opioid administration," Brit. J. Anaesth., 1998; 81:3-7 |
| AN | van Laar, et al., "Future delivery systems for apomorphine in patients with Parkinson's disease," Parkinson's Disease: Advances in Neurology, Lippincott Williams & Wilkins, Philadelphia, 1999; 80: 535-544. |
| AO | Goldstein, et al., "Vasculogenic female sexual dysfunction: vaginal engorgement and clitoral erectile insufficiency syndromes," Int J Impotence Res, 1998; 10(Suppl. 2) S84-S90. |
| AP | Chustecka, "New treatments for erectile dysfunction", Scrip Reports, PJB Publications Limited, (1998). |
| AQ | Gower et al., "Antagonism of Drug-induced Yawning and Penile Erections in Rats", European J of Pharmac, Vol 122 (1986) pp 239-244 |

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| EXAMINER | DATE CONSIDERED |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| U.S. PATENT DOCUMENTS | | | | | | | | | | | | | | |
| *EXAMINER INITIAL | | DOCUMENT NUMBER | | | | | | | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE | |
| | BA | 5 | 9 | 8 | 5 | 8 | 8 | 9 | 11/16/99 | El-Rashidy, et al. | 514 | 284 | 06/22/98 | |
| | BB | 5 | 9 | 9 | 4 | 3 | 6 | 3 | 11/30/99 | El-Rashidy, et al. | 514 | 284 | 08/24/98 | |
| | BC | 6 | 1 | 2 | 1 | 2 | 7 | 6 | 09/19/00 | El-Rashidy, et al. | 514 | 284 | 06/22/98 | |
| | BD | 6 | 1 | 9 | 9 | 9 | 9 | 2 | 02/27/01 | El-Rashidy, et al. | 424 | 434 | 07/02/99 | |
| | BE | 6 | 2 | 0 | 0 | 5 | 9 | 1 | 03/13/01 | Hussain, et al. | 424 | 434 | 12/10/98 | |
| | BF | 6 | 2 | 0 | 0 | 9 | 8 | 3 | 03/13/01 | El-Rashidy, et al. | 514 | 284 | 11/15/99 | |
| | BG | 6 | 2 | 9 | 1 | 4 | 7 | 1 | 09/18/01 | Kling, et al. | 514 | 284 | 12/17/98 | |
| FOREIGN PATENT DOCUMENTS | | | | | | | | | | | | | | |
| | | DOCUMENT NUMBER | | | | | | | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
| | | | | | | | | | | | | | YES | NO |
| | BH | 9 | 9 | 0 | 9 | 8 | 2 | 8 | 03/04/99 | WO (A1) | A01N | 43/42 | | |
| | BN | | | | | | | | | | | | | |
| | BJ | | | | | | | | | | | | | |
| | BK | | | | | | | | | | | | | |
| | BF | | | | | | | | | | | | | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | | |
| | BM | Uprima: Scientific Discussion re: Apomorphine in treatment of erectile dysfunction, Abbott Laboratories Ltd. (2001). | | | | | | | | | | | | |
| | BN | Summary of Product Characteristics of Apomorphine 2mg and 3 mg sublingual tablets, Abbott Laboratories Ltd. (2001). | | | | | | | | | | | | |
| | BO | Heaton et al., "The Characterization of a Bio-Assay of Erectile Function in a Rat Model", J of Urology, Vol 145 (1991) pp 1099-1102 | | | | | | | | | | | | |
| | BP | Heaton et al., "A Therapeutic Taxonomy of Treatments for Erectile Dysfunction: An Evolutionary Imperative", Intl J of Impotence Research, Vol 9 (1997) pp 115-121 | | | | | | | | | | | | |
| | BQ | Segraves et al., "Effects of Psychotropic Drugs on Human Erection and Ejaculation", Arch Gen Psychiatry, Vol 46 (1989) | | | | | | | | | | | | |
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| U.S. PATENT DOCUMENTS | | | | | | | | | | | | | | |
| *EXAMINE R INITIAL | CA | DOCUMENT NUMBER | | | | | | | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE | |
| | CA | 6 | 3 | 9 | 6 | 4 | 3 | 7 | 10/23/01 | El-Rashidy, et al. | 424 | 464 | 06/29/00 | |
| | CB | 6 | 3 | 4 | 2 | 2 | 5 | 1 | 01/29/02 | Illum, et al. | 424 | 501 | 06/02/00 | |
| | CC | 6 | 3 | 9 | 5 | 7 | 4 | 4 | 05/28/02 | Adams, et al. | 514 | 284 | 06/18/99 | |
| | CD | 6 | 4 | 3 | 6 | 9 | 5 | 0 | 05/23/02 | Achari, et al. | 514 | 284 | 06/16/99 | |
| | CL | 6 | 5 | 1 | 4 | 4 | 8 | 2 | 02/04/03 | Bartus, et al. | 514 | 220 | 09/19/00 | |
| | CL | 6 | 5 | 6 | 6 | 3 | 6 | 8 | 05/20/03 | El-Rashidy, et al. | 514 | 284 | 10/23/01 | |
| | CG | 6 | 5 | 2 | 8 | 5 | 2 | 1 | 03/04/03 | Ruff, et al. | 514 | 284 | 11/14/01 | |
| FOREIGN PATENT DOCUMENTS | | | | | | | | | | | | | | |
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| | | | | | | | | | | | | | YES | NO |
| | CH | 9 | 0 | 2 | 7 | 9 | 0 | 5 | 06/10/99 | WO(A1) | A61K | 9/00 | | |
| | CI | 6 | 9 | 3 | 8 | 4 | 4 | 7 | 08/05/99 | WO(A1) | A61F | 6/06 | | |
| | CJ | 9 | 9 | 6 | 6 | 9 | 0 | 9 | 12/29/99 | WO (A2) | A61K | 31/00 | | |
| | CK | 9 | 9 | 6 | 6 | 9 | 3 | 3 | 12/29/99 | WO (A1) | A61K | 31/505 | | |
| | CL | 6 | 0 | 3 | 5 | 4 | 5 | 7 | 06/22/00 | WO (A1) | A61K | 31/485 | | |
| | CM | 9 | 5 | 2 | 8 | 9 | 3 | 0 | 11/02/95 | WO (A1) | A61K | 31/485 | | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | | |
| | CN | Laduron et al., "Domperidone, a Specific in Vitro Dopamine Antagonist, Devoid of In Vivo Central Dopaminergic Activity", Biochem Pharmac., Vol 28 (1979) pp 2161-2165 | | | | | | | | | | | | |
| | CO | Bladessarini et al., "Preclinical Studies of the Pharmacology of Aporphines", Basic Pharmac., Vol 1 (1981) | | | | | | | | | | | | |
| | CP | Lal et al., "Effect of Domperidone on Apomorphine-Induced Growth Hormone Secretion in Normal Men", J or Neurotransmission, Vol 54 (1982) pp 75-84 | | | | | | | | | | | | |
| | CQ | Heaton, "Neural and Pharmacological Determinants of Erection", Intl j of Impotence Research, Vol 10 Supp 2 (1998) pp S34-S39 | | | | | | | | | | | | |
| | CR | Gancher et al., "Peripheral Pharmacokinetics of Apomorphine in Humans", Annals of Neurology, Vol 26 (1989) | | | | | | | | | | | | |
| | CS | Heaton et al., "Recovery of Erectile Function by the Oral Administration of Apomorphine", Urology, Vol 45 No 2 (1995) | | | | | | | | | | | | |
| | CT | Sachs et al., "Effects of Copulation on Apomorphine-Induced Erection in Rats", Pharmacol Biochem & Behavior, Vol 48 No 2 (1994) pp 423-428 | | | | | | | | | | | | |
| | CU | "Oral Medication for Impotence", TLC Pharmacy Men's Newsletter, Issue 2; (downloaded from the internet at http://tlcpharmacy.com/mends_newsletter_2.html on Nov. 15, 1998) | | | | | | | | | | | | |
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| *EXAMINER INITIAL | | DOCUMENT NUMBER | | | | | | | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE | |
| | DA | 5 | 2 | 7 | 0 | 6 | 0 | 6 | 06/23/98 | El-Rashidy | 514 | 284 | | |
| | DB | 4 | 0 | 8 | 0 | 4 | 5 | 6 | 03/21/78 | Seidelmann, et al. | 424 | 258 | | |
| | DC | 6 | 4 | 0 | 3 | 6 | 0 | 5 | 06/11/02 | Heaton, et al. | 514 | 284 | | |
| | DD | | | | | | | | | | | | | |
| | DE | | | | | | | | | | | | | |
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| | DG | | | | | | | | | | | | | |
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| | DH | 0 | 0 | 7 | 6 | 5 | 0 | 9 | 12/21/00 | WO(A1) | A61K | 31/44 | | |
| | DI | 0 | 1 | 7 | 4 | 3 | 5 | 8 | 10/11/01 | WO(A1) | A61K | 31/4375 | | |
| | DJ | 0 | 1 | 7 | 6 | 6 | 0 | 2 | 10/18/01 | WO (A1) | A61K | 31/473 | | |
| | DK | 0 | 1 | 8 | 2 | 0 | 0 | 6 | 11/08/01 | WO(A1) | A61K | 9/72 | | |
| | DL | | | | | | | | | | | | | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | | |
| | DM | Moyer, Female Sexual Dysfunction, Urch Publishing (August 1998) | | | | | | | | | | | | |
| | DN | Lal, et al., "Apomorphine in the Evaluation of Dopaminergic Function in Man," Prog. Neuro-Psychopharmacol. & Biol. Psychiat. vol 12, pp. 117-164 (1988) | | | | | | | | | | | | |
| | DO | Harvard Scientific (Harvard Scientific Corp., "Harvard Scientific Acquires Rights to Oral Treatment for Both Male and Female Sexual Dysfunction, pp. 1-3, (Jun. 12, 1998) | | | | | | | | | | | | |
| | DP | New Perspectives in Management of Female Sexual Dysfunction: Agenda for Oct. 23-25, 1998 conference in Maine | | | | | | | | | | | | |
| | DQ | Essink, et al., "Selective and Quantitative Isolation and Determination of Apomorphine in Human Plasma", J of Chromatography, Vol 570 (1991) pp 419-424 | | | | | | | | | | | | |
| | DR | Gancher et al., "Absorption of Apomorphine by Various Routes in Parkinsonism", Movement Disorders, Vol 6 No 3 (1991) pp 212-216 | | | | | | | | | | | | |
| | DS | Lal et al., "Effect of Bromocriptine in Patients with Apomorphine-Responsive Erectile Impotence: An Open Study", J Psychiatr Neurosci, Vol 16 No 5 (1991) | | | | | | | | | | | | |
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| | EA | | | | | | | | | | | | | |
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| | EB | 0 | 2 | 2 | 4 | 2 | 0 | 2 | 03/28/02 | WO(A1) | A61K | 31/44 | | |
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| | ED | 2 | 0 | 02 | 02 | 42 | 0 | 2 | 03/28/02 | WO(A1) | A61K | | | |
| | EE | 1 | 9 | 99 | 06 | 69 | 3 | 9 | 12/29/99 | WO(A2) | A61K | | | |
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| | EG | 0 | 6 | 8 | 9 | 4 | 3 | 8 | 01/03/96 | EP | A61K | 31/485 | | |
| | EH | 1 | 2 | 2 | 4 | 9 | 3 | 3 | 07/24/02 | EP | A61K | 31/505 | | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | | |
| | EI | Fourcroy, "Issues and Priorities in the Development of Drug Treatments for Female Sexual Dysfunction", International J. Of Impotence Research, 10 Supp 2 (1998) | | | | | | | | | | | | |
| | EJ | Fernandez-Guasti et al., "Separation of Dopaminergic and Serotonergic Inhibitory Mechanisms in the mediation of Estrogen-Induced Lordosis Behavior in the Rat", Pharm. Biochem. & Behavior, Vol 27 pp 93-98 | | | | | | | | | | | | |
| | EK | Heaton et al., "Effects of Castration and Exogenous Testosterone Supplementation in an Animal Model of Penile Erection", J of Urology, Vol 151 (1994) pp 797-800 | | | | | | | | | | | | |
| | EL | Goodman & Gilman, Pharmacological Basis of Therapeutics, 9 th Ed. pp 1-9 | | | | | | | | | | | | |
| | EM | Pehek et al., "Apomorphine and Haloperidol, but not Domperidone, Affect Penile Reflexes in Rats", Pharm Biochem & Behavior, Vol 31 (1998) pp 201-208 | | | | | | | | | | | | |
| | EN | Danjou et al., "Assessment of Erectogenic Properties of Apomorphine and Yohimbine in Man", Br J clin Pharmac, Vol 26 (1988) 733-739 | | | | | | | | | | | | |
| | EO | Tagliamonte et al., "Possible Stimulatory Role of Brain Dopamine in the Copulatory Behavior of Male Rats", Pharmac Biochem and Behavior, Vol 2 (1974) pp 257-260 | | | | | | | | | | | | |
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| | | | | | | | | | | | | | | | | | | 20 02 01 65 1 2 2 | 11/07/02 | Heaton et al. | 514 | 1 | 05/02/02 |
| | | | | | | | | | | | | | | | | | | 20 02 01 65 2 4 9 | 11/07/02 | Achari et al. | 514 | 289 | 01/31/02 |
| | | | | | | | | | | | | | | | | | | 20 02 01 93 3 9 7 | 12/19/02 | Achari et al. | 514 | 295 | 01/31/02 |
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| | | | | | | | | | | | | | | | | | | 20 93 00 17 1 1 5 | 01/25/03 | Rabinowitz et al. | 424 | 46 | 05/15/02 |
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| | | | | | | | | | | | | | | | | | | 20 02 00 02 1 7 6 | 01/03/02 | Gupta et al. | 514 | 284 | 03/29/01 |
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| | | | | | | | | | | | | | | | | | | 20 02 00 35 1 3 1 | 03/21/02 | El-Rashidy et al. | 514 | 321 | 10/03/01 |
| | | | | | | | | | | | | | | | | | | 20 02 00 86 8 7 6 | 07/04/02 | Ruff et al. | 514 | 295 | 03/14/01 |
| | | | | | | | | | | | | | | | | | | 20 02 01 27 1 8 8 | 09/12/02 | Platz et al. | 424 | 46 | 02/01/02 |
| | | | | | | | | | | | | | | | | | | 20 02 01 61 0 1 7 | 10/31/02 | Achari et al. | 514 | 288 | 01/31/02 |
| | | | | | | | | | | | | | | | | | | 20 03 00 91 5 1 2 | 05/15/03 | Adjei et al. | 424 | 46 | 09/03/02 |
| | | | | | | | | | | | | | | | | | | 20 02 00 6 9 3 3 | 01/17/02 | Gupta et al. | 514 | 295 | 03/14/01 |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | | | | | | | | | | | | | | | | |
| | | DOCUMENT NUMBER | | | | | | | | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | | | | | | | | | |
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| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | | | | | | | | | | | |
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| LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary) | | | | APPLICANT(S): John STANIFORTH et al. | | | | | | | | | | |
| | | | | FILING DATE: October 6, 2005 | | GROUP: To be assigned | | | | | | | | |
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| | GA | 20 | 04 | 02 | 04 | 4 | 3 | 0 | 10/14/04 | STANIFORTH, et al. | 514 | 295 | | |
| | GB | 20 | 04 | 02 | 04 | 4 | 4 | 0 | 10/14/04 | STANIFORTH, et al. | 514 | 295 | | |
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| | GJ | 00 | 0 | 2 | 7 | 3 | 6 | 3 | 05/18/00 | WO | | | | |
| | GK | | | | | | | | | | | | | |
| OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | | |
| | GL | "Inhaled Apomorphine Promising for Erectile Dysfunction Treatment," Pharmaceutical Journal; 09 August 03; United Kingdom; Vol. 271, no. 7261, p. 170 | | | | | | | | | | | | |
| | GM | | | | | | | | | | | | | |
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